

Applicants: Jonathan M. Barasch et al.  
U.S. Serial No.: 09/980,853, national stage of PCT/US00/12536  
National Entry Date: November 2, 2001  
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computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application.

Accordingly, in accordance with 37 C.F.R. §1.821(e), please use the computer readable form filed in PCT International Application No. PCT/US00/12536 on May 4, 2000 as the computer readable form for the instant application.

#### **INFORMATION DISCLOSURE STATEMENT**

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (**Exhibit C**). These references were previously submitted or cited in connection with the prosecution of U.S. Serial No. 09/305,029. The subject application claims benefit of the filing date of U.S. Serial No. 09/305,029 under 35 U.S.C. §120. According to 37 C.F.R. §1.98(d), copies of patents or publications that were previously cited by, or submitted to, the Patent Office in connection with such prior applications need not accompany the Information Disclosure Statement. Accordingly, copies of the following references are not attached to this Information Disclosure Statement:

1. PCT International Publication No. WO 00/41713, published July 20, 2000;

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2. Barasch, J., L. Pressler, J. Connor, and A. Malik. 1996. A ureteric bud cell line induces nephrogenesis in two steps by two distinct signals. *Am. J. Physiol.* 271: F50-F61;
3. Barasch, J., J. Qiao, G. McWilliams, D. Chen, J.A. Oliver, and D. Herzlinger. 1997. Ureteric bud cells secrete multiple factors, including bFGF, which rescue renal progenitors from apoptosis. *Am. J. Physiol.* 273: F757-F767;
4. Barasch, J., J. Yang, J. Qiao, P. Tempst, H. Erdjument-Bromage, W. Leung, J.A. Oliver. May, 1999. Tissue inhibitor of metalloproteinase-2 stimulates mesenchymal growth and regulates epithelial branching during morphogenesis of the rat metanephros. *J. Clin. Invest.* 103: 1299-1307;
5. Bard, J.B.L. and A.S.A. Ross. LIF, the ES-cell inhibition factor, reversibly blocks nephrogenesis in cultured mouse kidney rudiments. *Development* 113: 193-198, 1991;
6. Boccaccio, C., M. Ando, L. Tamagnone, A. Bardelli, P. Michieli, C. Battistini, and P.M. Comoglio. 1998. Induction of epithelial tubules by growth factor HGF depends on the STAT pathway. *Nature* 391: 285-288;
7. Bonni, A., Y. Sun, M. Nadal-Vicens, A. Bhatt, D. A. Frank, I. Rozovsky, N. Stahl, G.D. Yancopoulos, and M.E. Greenberg. 1997. Regulation of gliogenesis in the central nervous system by the JAK-STAT signaling pathway. *Science* 278: 477-483;
8. Grobstein, C. 1955. Inductive interaction in the development of the mouse metanephros. *J. Exp. Zool.* 130: 319-339;
9. Gruenwald, P. 1943. Stimulation of nephrogenic tissue by normal and abnormal inductors. *Anat. Rec.* 86: 321-335;
10. Hartner, A. et al. Cytokine-induced expression of leukemia inhibitory factor in renal mesangial cells. *Kidney International* 45: 1562-1571, 1994;
11. Hartner, A. et al. Renal mesangial cells have the capacity to synthesize and react to leukemia inhibitory factor. *Ann. N.Y. Acad. Sci.* 762 (Interleukin-6-Type Cytokines): 424-425, 1995 (Abstract);

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12. Herzlinger, D., J. Qiao, D. Cohen, N. Ramakrishna, and A.M.C. Brown. 1994. Induction of Kidney epithelial morphogenesis by cells expressing *Wnt-1*. *Develop. Biol.* 166: 815-818;
13. Karavanova, I.D., L.F. Dove, J.H. Resau, and A.O. Perantoni. 1996. Conditioned media from a rat ureteric bud cell line in combination with bFGF induces complete differentiation of isolated metanephric mesenchyme. *Development* 122: 4159-4167;
14. Kispert, A., S. Vainio, A.P. McMahon. 1998. *Wnt-4* is a mesenchymal signal for epithelial transformation of metanephric mesenchyme in the developing kidney. *Development* 125: 4225-4234;
15. Mayer, M., Bhakoo, K., and M. Noble. 1994. Ciliary Neurotrophic factor and leukemia inhibitory factor promote the generation, maturation and survival of oligodendrocytes in vitro. *Development* 120: 143-153;
16. Morel, D.S. et al. Renal synthesis of leukemia inhibitory factor. *Cytokine* 12(3): 265-271, 2000 (Abstract);
17. Murphy, M., K. Reid, D.J. Hilton, and P.F. Bartlett. 1991. Generation of sensory neurons is stimulated by leukemia inhibitory factor. *Proc. Natl. Acad. Sci. USA* 88: 3498-3501;
18. Murphy, M., K. Reid, M.A. Brown, P.F. Bartlett. 1993. Involvement of leukemia inhibitory factor and nerve growth factor in the development of dorsal root ganglion neurons. *Development* 117: 1173-1182;
19. Murphy, M., K. Reid, M. Ford, J. B. Furness, and P. F. Bartlett. 1994. FGF2 regulates proliferation of neural crest cells, with subsequent neuronal differentiation regulated by LIF or related factors. *Development* 120: 3519-3528;
20. Perantoni, A.O., L.F. Dove and I. Karavanova. 1995. Basic fibroblast growth factor can mediate the early inductive events in renal development. *Proc. Natl. Acad. Sci. USA*. 92: 4696-4700;
21. Sariola, H., P. Ekblom, S. Henke-Fahle. 1989. Embryonic neurons as *in vitro* inducers of differentiation of nephrogenic mesenchyme. *Devel. Biol.* 132: 271-281;

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22. Stark, K., S. Vainio, G. Vassileva, A. P. McMahon. 1994. Epithelial transformation of metanephric mesenchyme in the developing kidney regulated by *Wnt-4*. *Nature* 372: 679-683;
23. Taupin, J.L. et al. HILDA-LIF urinary excretion during acute kidney rejection. *Transplantation* 53(3): 655-658, 1992 (Abstract); and
24. Wallner, E.I. et al. Growth factors in metanephric development. *Renal Failure* 20(2): 331-341, 1998 (Abstract).

Applicants are submitting this Information Disclosure Statement under 37 C.F.R. §1.97(b)(3) before the mailing of a first Office Action on the merits. Accordingly, no fee is deemed necessary in connection with the filing of this Information Disclosure Statement.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone the number provided below.


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No fee, other than the enclosed \$65.00 surcharge for filing the attached Declaration, is deemed necessary in connection with the filing of this Communication and Information Disclosure Statement. However, if any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, BOX PCT, Washington, D.C. 20231.

 3/5/02

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Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office			Atty. Docket No. 58040-A-PCT-US/JPW/ADM		Serial No. 09/980,853				
<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)					Applicants: Jonathan M. Barasch et al.						
					Filing Date: November 2, 2001		Group Art Unit				
<b>U.S. PATENT DOCUMENTS</b>											
Examiner Initial		Document Number			Date	Name	Class	Subclass	Filing Date if Appropriate		
<b>FOREIGN PATENT DOCUMENTS</b>											
		Document Number			Date	Country	Class	Subclass	Translation		
									Yes	No	
		0	0	4	1	7	1	3	7/20/00	PCT	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>											
		Barasch, J. , L. Pressler, J. Connor, and A. Malik. 1996. A ureteric bud cell line induces nephrogenesis in two steps by two distinct signals. <i>Am. J. Physiol.</i> 271: F50-F61;									
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Form PTO-1449 (REV. 8-83)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		Atty. Docket No. 58040-A-PCT-US/JPW/ADM	U.S. Serial No. 09/980,853		
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		Hartner, A. et al. Cytokine-induced expression of leukemia inhibitory factor in renal mesangial cells. <i>Kidney International</i> 45: 1562-1571, 1994;					
		Hartner, A. et al. Renal mesangial cells have the capacity to synthesize and react to leukemia inhibitory factor. <i>Ann. N.Y. Acad. Sci.</i> 762 (Interleukin-6-Type Cytokines): 424-425, 1995 (Abstract);					
		Herzlinger, D., J. Qiao, D. Cohen, N. Ramakrishna, and A.M.C. Brown. 1994. Induction of Kidney epithelial morphogenesis by cells expressing <i>Wnt-1</i> . <i>Develop. Biol.</i> 166: 815-818;					
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		Murphy, M., K. Reid, M. Ford, J. B. Furness, and P. F. Bartlett. 1994. FGF2 regulates proliferation of neural crest cells, with subsequent neuronal differentiation regulated by LIF or related factors. <i>Development</i> 120: 3519-3528;					
		Perantoni, A.O., L.F. Dove and I. Karavanova. 1995. Basic fibroblast growth factor can mediate the early inductive events in renal development. <i>Proc. Natl. Acad. Sci. USA</i> . 92: 4696-4700;					
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